UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

LOIS ILICH KOHO,

Plaintiff,

v.

FOREST LABORATORIES, INC., *et al.*,

Defendants.

Case No. C05-667RSL

ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

This matter comes before the Court on "Defendants' Motion For Summary Judgment." Dkt. # 96. Having reviewed the memoranda, declarations, and exhibits submitted by the parties, and the arguments presented at the March 19, 2015 hearing on this motion, the Court finds as follows.

I. BACKGROUND[1]

Ray Ilich was prescribed the Selective Serontin Reuptake Inhibitor (SSRI) Celexa by his physician, Dr. Randall Gould, on August 7, 2002 to treat situational depression. Dkt. # 39-16 (Gould Decl.) at 2. For two days prior to receiving his prescription, Ilich had received Celexa from plaintiff, his wife. Dkt. # 97-1 (Koho Dep.) at 6 (31:1-7). Ilich returned to Dr. Gould on August 9, reporting that his condition had deteriorated and that he was experiencing suicidal

[1] Defendants move to exclude Exhibit A to plaintiff's opposition brief, which is a "Statement of Undisputed Material Facts." The Court did not consider this exhibit in ruling on the instant motion.

ideation. Dkt. # 39-16 at 2. On August 13, seven days after being prescribed Celexa, Ilich committed suicide. Id. Ilich was 48 years old. Dkt. # 39-18 (Autopsy) at 1.

The New Drug Application (NDA) for Celexa was submitted to the FDA on May 7, 1997. Dkt. # 48 (Defs.' Resp. MSJ) at 12. The FDA approved Celexa on July 17, 1998, for the treatment of depression in adults. Id. In 2002, the risk of suicide was referenced on the Celexa warning label as follows:

> The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Celexa should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

Dkt. #39-19 (Label) at 2. As the FDA gradually became more aware of the suicidality risks posed by SSRIs, the agency began mandating more stringent warnings. On March 19, 2004, the FDA required that the Celexa warning label be modified to add a new subsection entitled "Clinical Worsening and Suicide" which read:

> Patients with major depressive disorder, both adult and pediatric, can experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Although there has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients, a causal role for antidepressants in inducing such behaviors has not been established. **Nevertheless, patients being treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of a course of drug therapy, or at the time of dose changes, either increases or decreases . . . Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications should be alerted about the need to monitor patients for the emergence of agitation, irritability, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers.**

Dkt. #51 (Konnerth Decl.) Ex. Y at 2 (emphasis in original). On May 1, 2007, the FDA continued to mandate the following language: "**All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the**

initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases." Id. Ex. MM at 3 (emphasis in original).[2]

Since approving the first SSRI, Prozac, in 1987, the FDA has received three citizen petitions requesting that approval be withdrawn based on claims that the drug caused suicidality. Dkt. # 48 at 12-15. These petitions, which were reviewed in 1990, 1991, and 1997, were rejected due to the FDA's conclusion that there was insufficient causal evidence to support an association between SSRIs and suicidality. Id. at 14. Over time, the FDA began mandating suicidality warnings concerning pediatric and young adult patients, but it has yet to find an increased risk of suicide in adults taking SSRIs. See id. at 16-19.

Plaintiff filed her Complaint in the above-captioned case in April 2005, representing herself to be the personal representative of Mr. Ilich's estate. Dkt. # 1 (Compl.) at 1. Plaintiff claims that Mr. Ilich's death was caused by defendants' failure to warn about risks associated with Celexa. Specifically, plaintiff argues that, at some point prior to Ilich being prescribed the drug, defendants "should have added a warning of increased risk of suicidal thoughts and behaviors early in treatment, including an emphasis on the importance of communicating the risk to family members who would be the first to observe any telltale changes in behavior." Dkt. # 54 at 4.[3]

This case was transferred to the Eastern District of Missouri in 2006 for consolidated pre-trial proceedings. See Dkt. # 26 (Transfer Order) at 1. On August 28, 2013, the case was remanded to this Court. Dkt. # 28 (Remand Order) at 1. On April 30, 2014, this Court granted plaintiff's motion for partial summary judgment. Dkt. # 64 (Order). In ruling that defendants could not use Washington's learned intermediary doctrine as an affirmative defense, the Court notes that it was clear from Dr. Gould's declaration and deposition testimony that Gould would

[2] This is the latest version of the Celexa warning presented to this Court.

[3] "[T]he precise warning at issue in this case involves the increased risks of suicidal thoughts and behaviors during the initial phase of drug treatment and the recommendation that family members and caregivers monitor behavior early in treatment." Id. at 13.

have acted differently in Ilich's case had the risks conveyed by plaintiff's proposed warning been known to him. Id. at 15. The Court also clarified that plaintiff's proposed warning was not a warning that Celexa "increases the likelihood of suicide among adult patients." Id. at 13.

In August 2014, defendants filed the instant motion, Dkt. # 96, and a motion to exclude the testimony of plaintiff's expert witness for specific causation, Dr. David Healy, Dkt. # 98. In its motion for summary judgment, defendants argued that plaintiff had never been appointed the personal representative of Ilich's estate. Dkt. # 96 at 11. In response, plaintiff's counsel admitted that she had not in fact been appointed personal representative, that the Complaint was erroneous, and that the probate estate had yet not been opened. Dkt. # 101 (Pl. Resp.) at 7; Dkt. # 101-2 (Yackulic Decl.) at 1-2. Plaintiff's counsel claimed that this was a mistake and that counsel sought to rectify the problem as soon as it was brought to their attention. Dkt. # 101-1 at 1. Probate was opened in state court and plaintiff was made the estate's personal representative on September 10, 2014. Dkt. # 103 (Yackulic Decl. and Order). Defendants filed a motion to dismiss for lack of subject matter jurisdiction shortly thereafter, Dkt. # 107, which the Court denied, Dkt. # 125. The Court has also denied defendants' motion to exclude Dr. Healy. Dkt. # 126.

II. STANDARD FOR SUMMARY JUDGMENT

Summary judgment is appropriate if, viewing the evidence and all reasonable inferences drawn therefrom in the light most favorable to the nonmoving party, the moving party shows that "there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); Torres v. City of Madera, 648 F.3d 1119, 1123 (9th Cir. 2011). The moving party "bears the initial responsibility of informing the district court of the basis for its motion." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Where the nonmoving party will bear the burden of proof at trial, the moving party may meet its burden by "pointing out . . . that there is an absence of evidence to support the nonmoving party's case." Id. at 325. Once the moving party has satisfied its burden, the nonmoving party must then set out "specific

facts showing that there is a genuine issue for trial" in order to defeat the motion. Id. at 324. "The mere existence of a scintilla of evidence in support of the non-moving party's position" is not sufficient; this party must present probative evidence in support of its claim or defense. Arpin v. Santa Clara Valley Transp. Agency, 261 F.3d 912, 919 (9th Cir. 2001); Intel Corp. v. Hartford Accident & Indem. Co., 952 F.2d 1551, 1558 (9th Cir. 1991). An issue is genuine only if there is a sufficient evidentiary basis on which a reasonable fact finder could find for the nonmoving party. In re Barboza, 545 F.3d 702, 707 (9th Cir. 2008).

III. DISCUSSION

A. Plaintiff's Failure to Become the Representative of Mr. Ilich's Estate Prior To September 2014 Is Not Fatal to Her Action.

Defendants argue that plaintiff cannot sustain this action because she was not the personal representative of Mr. Ilich's estate when the Complaint was filed, and a proper action on behalf of this estate is now time-barred under Washington's three-year statute of limitations for product liability claims. Dkt. # 96 at 10-11; R.C.W. § 7.72.030(c). Washington law provides that only a court-appointed personal representative has the authority to assert claims on the behalf of a deceased person. Masood v. Saleemi, 2007 WL 2069853, at *3 (W.D. Wash. July 13, 2007) aff'd, 309 F. App'x 150 (9th Cir. 2009). Plaintiff did not in fact become the personal representative of the estate until September 2014. Dkt. # 103. The question is whether this entitles defendants to a favorable judgment.

The issue here is plaintiff's capacity to sue. Masood, 2007 WL 2069853, at *3. A defendant's challenge to a plaintiff's capacity must be made by "a specific denial, which must state any supporting facts that are peculiarly within the [defendant's] knowledge." Fed. R. Civ. P. 9(a)(1)(b). This denial "must be made" in a responsive pleading or by motion before pleading. See De Saracho v. Custom Food Mach., Inc., 206 F.3d 874, 878 (9th Cir. 2000) (citation omitted) (stating that a "specific negative averment" was necessary, quoting earlier language from Rule 9(a)). This Court concurs with others that have held that a general denial

based on lack of knowledge does not comport with this requirement. E.g., Wiwa v. Royal Dutch Petroleum Co., 2009 WL 464946, at * 5 n. 23 (S.D.N.Y. Feb. 25, 2009); Srock v. United States, 2006 WL 2460769, at * 3 (E.D. Mich. Aug. 23, 2006). Under Fed. R. Civ. P. 17(a)(3), the Court may not dismiss an action for "failure to prosecute in the name of the real party in interest" until, after an objection is made, "a reasonable time has been allowed for the real party in interest to ratify, join, or be substituted into the action." Precedent suggests that this Rule is meant to be invoked by parties who made an "understandable mistake." In re Phenylpropanolamine (PPA) Products Liab. Litig., 2006 WL 2136722, at * 3 (W.D. Wash. July 28, 2006) (citation omitted); see Goodman v. United States, 298 F.3d 1048, 1053-54 (9th Cir. 2002).

The Court fails to see the understandable mistake in plaintiff's failure to discover her lack of capacity to sue. Plaintiff's counsel offers no clear explanation for how this mistake was made. See Dkt. # 101-2. Nevertheless, the Court finds that defendants waived their capacity challenge. Defendants' Answers only generally denied plaintiff's capacity to sue based on defendants' lack of "knowledge or information," which is insufficient to invoke Rule 9(a), Srock, 2006 WL 2460769, at * 3; thus, their only proper challenge was made in the instant motion. In De Saracho, 206 F.3d at 878-79, the Court found that defendant had waived its challenge to plaintiff's capacity to sue where defendant had waited until the eve of trial, eight months after answering the Complaint, to bring this challenge. Trial is not imminent in this case, and the Ninth Circuit has allowed defendants to raise affirmative defenses outside of their initial pleadings where their delay did not prejudice the plaintiff. Lewis v. Russell, 838 F. Supp. 2d 1063, 1070 (E.D. Cal. 2012) (collecting Ninth Circuit cases); 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1295 (3d ed. 2014) (explaining that while not strictly speaking an affirmative defense, an objection to a party's "capacity, authority, or legal existence" could be analogized to an affirmative defense). However, the Court sees no reason why this challenge to plaintiff's capacity to sue is just now being raised after nine years of litigation, and finds no compelling precedent from this Circuit for permitting this late challenge.

The strongest support that defendants have for their challenge is Wiwa, 2009 WL 464946, at * 4, in which the Southern District of New York permitted a similar capacity challenge after years of litigation on the grounds that defendants had raised this challenge at the earliest "pragmatically possible" time. See id. at * 4 n. 16 (distinguishing De Saracho, 206 F.3d at 878-79 on the grounds that defendants there had discovered the relevant facts months prior to bringing their challenge) (also permitting the challenge because it did not prejudice plaintiffs). Defendants here have not explained their tardy challenge any better than plaintiff has explained her tardy appointment as representative. Dkt. # 104 (Defs.' Reply MSJ) at 5 (noting that information regarding the existence of an estate is "publicly available" and "available to anyone."). Defendants' challenge is waived.

B. Defendants' Causation Argument Fails Insofar As It Applies To Dr. Gould.

In arguing that plaintiff cannot meet her burden of proof, defendants rely heavily on the deposition testimony of Dr. Gould taken on August 1, 2014. Dkt. # 97-3 (Gould Dep. II). In its April 30, 2014 order, the Court held that Gould's declaration and December 13, 2013 deposition testimony had demonstrated that Gould "would have taken different steps with a different warning," and thus may not have prescribed Celexa to Ilich or may have taken Ilich off of the drug before he committed suicide. Dkt. # 64 at 15; Dkt. # 39-16 (Gould Decl.); Dkt. # 54-1 (Gould Dep. I). Defendants essentially ask the Court to reconsider this statement in light of Gould's more recent deposition. Defendants make two arguments regarding Gould. First, since Dr. Gould was already aware of the need to monitor Mr. Ilich for suicidal thoughts and actions after he began taking Celexa, defendants cannot be found liable for failing to provide a warning to this effect. Dkt. # 96 at 15-20. Second, because Dr. Gould has only discussed how he would have reacted to a warning suggesting that Celexa directly caused suicidality – a stronger warning than the one plaintiff proposes – and recently demonstrated uncertainty about what he would

have done differently in Ilich's case had he received such a warning, plaintiff cannot prove that her proposed warning would have caused Dr. Gould to act any differently.[4] Id. at 12-16.

The Court will not grant defendants summary judgment on these points. The Court starts with defendants' first argument. It is generally the case under Washington law that "a drug manufacturer's failure to warn a prescribing physician cannot be the proximate cause of the patient's injury if the physician was already aware of the risk involved in the use of the drug[.]" Wash. State Physicians Ins. Exch. & Ass'n v. Fisons Corp., 122 Wn.2d 299, 315 (1993). Had Dr. Gould testified that he knew that Ilich was at increased risk for suicide when he started Celexa, defendants would arguably be entitled to summary judgment. However, this was not Gould's testimony.

Dr. Gould testified that he knew when he prescribed Celexa that he should carefully evaluate Mr. Ilich "if" he had suicidal thoughts or actions after he started taking the drug. Dkt. # 97-3 at 9-10 (55:17-22; 56:19-22). Gould testified that, when he prescribed the drug, he knew to carefully evaluate Ilich if his depression worsened, id. at 8 (53:22-25); and that he warned Ilich to be alert for worsening depression, id. at 11 (57:4-7). Finally, Gould testified that he was alerted that Ilich could be suicidal on August 9, 2002, two days after he had prescribed the medication, id. at 6 (51:6-15); and it is clear from his testimony that he began "monitoring" Ilich for suicidality at that time, id. at 11 (57:14-22). But Gould never testified that he was aware of the increased suicidality risk conveyed by plaintiff's proposed warning when he prescribed Celexa on August 7, 2002. As the Court emphasized in its previous opinion, Celexa's 2002 warning only conveyed the suicide risk inherent in depression, and did not convey that patients

[4] Defendants repeatedly dismiss Gould's testimony about what he may have done differently as "speculation" and not "evidence." Dkt. # 96 at 13. To the extent that defendants attempt to argue that doctors are not allowed to opine about how they would have reacted to different warnings in a "failure-to-warn" case, and that such an opinion testimony may not be used to defeat summary judgment, defendants provide no precedent for this and are incorrect. See Schoenborn v. Stryker Corp., 801 F. Supp. 2d 1098, 1102 (D. Or. 2011). The only issue defendants properly raise is whether a jury could reasonably conclude that Gould would have acted differently given Gould's alleged equivocations on this point, which the Court discusses infra.

in the initial phase of drug treatment were at an "increased risk" for suicide. Dkt. # 64 at 15. The Court cannot rule out that had Gould been aware of this risk on August 7, his treatment plan then and thereafter would have been different (i.e., Gould may have taken Ilich off of the drug when suicidal ideation first manifested itself on August 9). Washington's "awareness of risk" rule therefore does not apply to preclude plaintiff's causation argument.

Furthermore, plaintiff has provided evidence that her proposed warning would have affected Dr. Gould's actions. Consistent with its prior opinion, the Court finds that Gould's previous testimony supports the notion that his treatment plan for Mr. Ilich would have been different had he received this warning. The occasional equivocations that defendants highlight in Gould's recent deposition (namely Gould's statement that "[I]t's impossible to go back there and know for sure what I would have done," Dkt. # 97-3 at 17 (67:7-10)) do not amount to a repudiation of this declaration. Construing Gould's testimony in the light favoring the nonmoving party and drawing all reasonable inferences in plaintiff's favor, the Court finds a genuine material fact issue. The Court rejects defendants' proximate causation argument with respect to Dr. Gould.

C. Defendants' Argument That Washington Law Would Impose No Duty To Issue Plaintiff's Proposed Warning Fails.

Defendants argue that they had no duty under Washington law to provide the type of warning that plaintiff proposes: a warning that would have conveyed that those taking Celexa were at increased risk for suicidal thoughts and behaviors during the initial phase of drug treatment and the recommendation that they be closely monitored. Defendants essentially argue that Washington law only requires manufacturers to warn about dangers that their products actually cause, and not other risks with which their products have merely been linked or correlated.

Read together, the relevant provisions of Washington's product liability statute suggest that a product warning is inadequate where it omits a danger or harm that the product could

cause.[5] R.C.W. § 7.72.030 (governing liability for product manufacturers). Washington precedent indicates that drug manufacturers have a duty to warn about risks "involved in" the use of prescription drugs. Estate of LaMontagne v. Bristol-Myers Squibb, 127 Wn. App. 335, 344 (2005) (to determine whether a warning is adequate, "The court must examine the meaning and context of the language and the manner of expression to determine . . . whether the warning portrays the risks involved in taking the prescription drug."); see Simonetta v. Viad Corp., 165 Wn.2d 341, 348 (2008) ("Under negligence law, a defendant has a duty to exercise ordinary care, and [a] manufacturer's duty of ordinary care is a duty to warn of hazards involved in the use of a product which are or should be known to the manufacturer.") (citation and internal quotation marks omitted). The Court finds no inconsistency between the proposed warning that Celexa takers initially face an increased risk of suicidality and Washington's rule that a warning must identify the "risks involved in" a product's use. Washington law appears to contemplate the type of warning proffered by plaintiff, which conveys risks attendant to starting on Celexa that the drug's 2002 warning label did not communicate.[6] Defendants' argument that as a matter

---

[5] (b) A product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the **likelihood that the product would cause the claimant's harm or similar harms**, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.

(c) A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about **a danger connected with the product** after it was manufactured. In such a case, the manufacturer is under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

R.C.W. § 7.72.030 (emphasis added).

[6] While the Court may further analyze what type of warning Washington law would have required or permitted when the Court crafts the jury instructions for this case, what is clear at this stage is that defendants are not entitled to summary judgment on this issue.

of law they cannot be found liable for failing to provide such a warning therefore fails.[7]

D. Plaintiff Has Raised a Triable Issue With Regards to Specific Causation.

Plaintiff's specific causation argument rests on the expert testimony of Dr. David Healy, who opines with a high degree of certainty that Celexa caused Mr. Ilich to commit suicide. Dkt. # 100-2 (Healy Report). Healy bases his conclusions on Ilich's medical history, the deposition testimony of Ilich's family members and Dr. Gould, and Healy's knowledge of SSRIs and other drugs; Healy puts particular emphasis on how soon after Ilich began taking Celexa that he committed suicide. See id.; Dkt. # 100-5 (Healy Dep.) at 8-9, 13 (101:18-25; 102:1-3; 104:9-19; 131:6-13; 134:18-22). Dr. Healy's opinions are reliable and relevant, and his testimony will be helpful to the jury; as the Court held in its order denying defendants' motion to exclude Healy under Daubert v. Merrill Dow Pharm., Inc., 509 U.S. 579, 589 (1993), this expert will be allowed to testify. Dkt. # 126. The Court finds that Healy's proffered testimony raises a genuine fact issue concerning whether Celexa caused Ilich's suicide, and so defendants are not entitled to summary judgment on this issue.

E. Plaintiff's Alleged Criminality Has No Bearing On This Action.

Defendants argue that because plaintiff provided Mr. Ilich with Celexa for two days before he received a prescription from Dr. Gould, in violation of Washington state law, she should not be allowed to sue defendants for whatever harm Celexa did to Mr. Ilich after it was properly prescribed. Dkt. # 96 at 23; R.C.W. §§ 69.41.010, 69.41.030. The only precedent defendants cite for this proposition is a 1935 Washington case, Paulson v. Montana Life Ins. Co., 181 Wash. 526, 537 (1935), which does not concern the same issues as this case and does not appear to be on point. Defendants have provided no adequate explanation for why they may not be found liable to plaintiff for their role in Mr. Ilich's death.

[7] For the purposes of deciding this motion, the Court need not make a ruling on whether or not Washington would follow a "heeding presumption," or a presumption that Dr. Gould would have heeded and followed an adequate warning regarding Celexa had such a warning been provided. This is a matter to be addressed at trial when deciding how the jury will be instructed.

IV. CONCLUSION

For all of the foregoing reasons, the Court DENIES defendants' motion for summary judgment. Dkt. # 96.

DATED this 8th day of April, 2015.

Robert S. Lasnik
United States District Judge